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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,241	10/23/2000	Nicole Barie	K 168	9230

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,241

Applicant(s)

BARIE ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

3. Applicant is advised that should claim 2 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for t-BSA as the photolinker, does not reasonably provide enablement for all photolinkers, or even all TRIMID-modified proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Throughout the specification, applicant has only discussed, and therefore enabled, the use of t-BSA as the photolinker for the dextran-coated surface of the invention. Applicant has not provided sufficient guidance or working examples for the recited dextran-coated surface with any other photolinker other than t-BSA. Since various molecules or classes of molecules can serve as photolinkers in various systems, and they all have different methods of action or functionality, undue experimentation would be required of one of skill in the art to find another photolinker, other than t-BSA, to use with the present invention. The nature of the invention and present state of the art does not allow one to use any photolinker with the recited invention with a predictable result with a reasonable expectation of success.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites the limitations "the dextran" and "said dextran-coating. There is insufficient antecedent basis for these limitations in the claim.

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9. Claim 4 recites the limitation "said polysaccharide". There is insufficient antecedent basis for this limitation in the claim.

10. Claim 5 recites the limitation "said protein". There is insufficient antecedent basis for this limitation in the claim.

11. Claim 8 recites the limitation "the surface of a mass-sensitive sensor". There is insufficient antecedent basis for this limitation in the claim. In addition, this limitation is vague and indefinite because a change in mass in any sensor will effect the functioning of the sensor in some capacity.

12. The recitation of "capable" in claim 9 renders the claim vague and indefinite. It is unclear, with this terminology, if the claim requires the sensor to use surface acoustic waves or not.

13. Claim 10 recites the limitation "the surface". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined

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was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Swan et al. (US Pat. 5,563,056). The reference discloses a process for the preparation of crosslinked matrices containing covalently immobilized chemical species and unbound releasable chemical species. According to the reference, polymers may be covalent immobilized in an insoluble 3-D crosslinked matrix, which is preferably formed as a coating upon a surface. A desired chemical specie and a polymeric coupling compound such as a photoderivatized polymer having multiple photoreactive groups are brought into proximity to each other. Upon activation, bonding occurs (abstract and cols. 2-3). Dextran may be the polymer from which the coupling compound is derived (col. 3, line 62). In addition, the photoreactive groups of the reference may be diazirines, such as 3-trifluoromethyl-3-phenyldiazirine (col. 5, line 55).

16. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbell et al. (US Pat. 5,529,914). The reference discloses interfacial polymerization to form a membrane on the surface of a biological membrane. Tissue is directly coated with photoinitiator, which is immersed in macromer solution, and immediately irradiated. This results in a thin polymer coat (col. 9). Dextran may be the macromer of the reference (col. 11, lines 19-54).

17. Claims 1 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Chabreck et al. (US Pat. 6,099,122). The reference discloses a novel coating process that comprises the use of a functional photoinitiator. A photoinitiator is reacted with a polymer to form a macroinitiator, and a thin film of the macroinitiator is applied to a surface, which is then

irradiated (cols. 39-41). Among the polymers useable with this method are dextran and aminated dextran (col. 4, lines 28-42).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Chai-Gao et al. (US Pat. 5,858,802).

Swan et al. and Hubbell et al. teach coating processes, as previously discussed. However, the references do not teach TRIMID modification or the use of BSA.

Chai-Gao et al. teach a method for making a device including a substrate and at least one biologically active substance bound to the surface of the substrate. The device is obtained by simultaneous or sequential reaction of the substrate and of the substance with a bifunctional coupling agent in which one of the functional groups may be photoactivated. The photoactivator is preferably a TRIMID-modified protein, such as T-BSA (cols. 3-5).

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator of Chai-Gao et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Chai-Gao et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Chai-Gao et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use aminodextran instead of dextran as the polymer because the two molecules differ only by 1 substitution, which is not viewed as detrimentally altering the binding capability of the dextran.

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22. Claims 2-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Wessa et al. (WO 97/43631)

Swan et al. and Hubbell et al. teach coating processes, as previously discussed. However, the references do not teach TRIMID modification, the use of BSA or polyimide, or application to biological sensors.

Wessa et al. teach a process for producing a sensor for detecting proteins. The sensor consists of a sensor body, one surface of which is coated with a polymer layer with receptor molecules bonded to said polymer layer. The bond between the polymer and the receptor molecules is provided by a photoreactive molecule that is covalent to the lysine of a receptor molecule and inserted into the polyimide. The photoreactive molecule is preferably TRIMID. The modified protein, which may be T-BSA, is bound to the polymer layer by UV irradiation. The sensor of the reference may be used as a surface acoustic wave sensor, which is interpreted as an electromechanical sensor. In addition, wave sensors are also interpreted as mass sensitive, as a difference in mass on the sensor will affect the results in some manner.

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator and polyimide of Wessa et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Wessa et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Wessa et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would

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have further been obvious to use aminodextran instead of dextran as the polymer because the two molecules differ only by 1 substitution, which is not viewed as detrimentally altering the binding capability of the dextran. In addition, it would have been obvious to apply the modified coating process of Wessa et al. and Swan et al. or Hubbell et al. to a biological sensor, as surface receptors are commonly used in sensing applications.

Conclusion

Claims 1-10 are rejected.

References: Barner et al., Siiman et al., Miyasaka et al., Golander et al., Jacobsen et al., and Sigrist et al. are cited as art of interest for teaching various coating processes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

February 5, 2002

Christopher L. Chin
CHRISTOPHER L. CHIN
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